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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,477	04/18/2001	Brendan Larder	VIP0011	8810

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EXAMINER

CLOW, LORI A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/836,477

Applicant(s)

LARDER ET AL.

Examiner

Lori A. Clow, Ph.D.

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8, 13, 16-25, 28-32 and 39-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8, 13, 16-25, 28-32 and 39-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicants' response, filed 25 July 2005, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-4, 8, 13, 16-25, 28-32 and 39-41 are currently pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4, 8, 13, 16-25, 28-32 and 39-41 are rejected under 35 U.S.C. 102(a) as being anticipated by Hertogs et al (Antimicro. Agents and Chemo. (March 2000) Vol. 44, pages 568-573). *This is a new grounds of rejection.*

Hertogs teaches the combined genotypic and phenotypic analysis of clinical isolates to reveal phenotypic resistance (abstract). Genetic sequence is obtained and mutation patterns are identified. High-throughput phenotyping and genotyping was performed to establish a database containing phenotypic resistance data and genotypic data for over 6,000 isolates. Correlative data analysis and mutational cluster analysis was performed to enable search for mutational patterns that accompanied phenotypic resistance profiles (page 568, column 2; page 569, column 1 under Materials and Methods), as in claims 1, 28, and 39.

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In regard to claims 2 and 40, Hertogs teaches a series of phenotypes; i.e. lamivudine therapy phenotype and zidovudine therapy phenotype (page 569, column 1, Results).

Hertogs teaches that the mutation pattern is specific to a therapy, as in claim 3 (abstract).

In regard to claim 4, the HIV sample is from a plasma sample (page 569, column 1, Materials and Methods).

In regard to claim 8, the mutations are base substitution mutations (abstract).

In regard to claim 13, the genetic sequence of HIV was from the protease and reverse transcriptase region of the virus (page 569, column 1, Materials and Methods).

In regard to claim 16, Hertogs teaches at least two mutations associated with phenotypic 3TC resistance (lamivudine) (abstract).

In regard to claim 17, the analysis includes cluster analysis (page 568, column 2, paragraph 2).

In regard to claim 18, the database comprises at least one mutation of HIV (page 569, column 1, Materials and Methods).

In regard to claims 19-22 and 29-32, Hertogs teaches various % frequencies of mutations (page 569, Table 1).

In regard to claims 23 and 24, the phenotype of HIV is a mean fold-change in resistance expressed as IC_{50} (page 569, column 1, Materials and Methods).

In regard to claims 25 and 41, Hertogs teaches a report of phenotype (page 571, Table 3).

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Conclusion

The objection to claim 5 has been withdrawn in view of the amendment canceling claim 5.

The rejection under 35 USC 101 has been withdrawn in view of the amendment canceling claims 26 and 27.

The rejections under 35 USC 112-2nd paragraph have been withdrawn in view of the amendments to the claims.

The rejection under 35 USC 102 (a) over Boden et al. has been withdrawn in view of Applicant's arguments with regard to the genotype/phenotype database.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the

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problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

October 28, 2005
Lori A. Clow, Ph.D.
Art Unit 1631

Lori A. Clow

**MARJORIE A. MORAN
PRIMARY EXAMINER**

Marjorie A. Moran
10/31/05